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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,279	01/17/2002	Alfred Bayati	1103326-0678	1319

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EXAMINER	
HARTLEY, MICHAEL G	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,279	BAYATI, ALFRED	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 January 2002* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Applicant's election of Group I in Paper No. 3/24/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for compounds identified by the method of claim 1 that are specifically named compounds, such as, a specific 5HT-3 agonist, does not reasonably provide enablement for "a compound" generally, meaning any compound identified by the method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides a compound that is identified by an *in vivo* test and a method of using the compound to treat dyspepsia. However, the compound claim (and its method of use) has no particular structure specifically disclosed in the specification for the compound. Thus, claiming a compound identified by a method amounts to a "reach through" claim which would encompass compounds which are

undefined at this time or known compounds. This is claiming into the future or even possible the past. For example, if a new compound that is prepared in the future is tested in the method of claim 1 and has activity, then it would be within the scope of the claim. However, the specification provides no guidance on how to make (or to use, such as, dosages, etc.) such a compound.

(2) The state of the prior art

The state of the prior art of performing a method of identifying a test compound to determine if it has a particular activity is known. Such include assays or in vivo test to determine efficacy. However, the state of the prior art to the actual compound(s) identified thereby is a matter of continual use of the method.

(3) The relative skill of those in the art

The relative skill of the those in the art is high in identifying any compound by solely its performance in a test. This would require first forming some compound with any structure and then subjecting to a test. This clearly would be only an invitation to experiment.

(4) The predictability or unpredictability of the art

The unpredictability of compound based on there in vivo efficacy of a disease is very unpredictable because of the diversity of the human body and the different mechanisms which affect the in vivo efficacy of a drug.

(5) The breadth of the claims

The claims are unduly broad as they encompass any compound that increases the maximum gastric accommodation capacity as compared to baseline prior to administration of the compound.

(6) The amount of direction or guidance presented

The amount of guidance does not define the compounds, as would be required for both making and using the compounds. The specification only provides a method of identifying an activity of the compounds. An assay for finding a product is not equivalent to a positive recitation of how to make the product.

(8) The quantity of experimentation necessary

The quantity of experimentation would be very high, as there is no disclosure on how to make the compounds, but only to check for their activity. Thus, this is only an invitation to experiment, but provides no disclosure on how to make or to use (as use would require a compound), as required.

Claims 6, 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide written description for the compounds and methods of use in claims 6, 8 and 9 because there are no limiting structural characteristics for the test compound. It is only defined as a compound that has an activity in the method of claim 1, which is an in vivo test for efficacy. Clearly, one skilled in the art would recognize that the inventors were not in possession of every compound that may have such activity. For example, say the method of claim 1 is tested with water and water provides an increase in maximum gastric accommodation, then claim 6 would encompass water. Also, it can be stated that one cannot be in possession of something prior to having identified it. Claims 6, 8 and 9 read on compounds that have not yet been identified, therefore, applicant is not in possession thereof.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6, 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative

relationships are: The structure of the compound, namely what elements are present and how they are bound to form a compound. The method of use is include because it requires administering said compound, but the structure of the compound is unknown.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoeltje (US 5,912,235).

Hoeltje discloses a method of identifying a compound for treatment of gastric capacity disorders comprising administering a test compound (e.g., an erythromycin A compound) to a dog (i.e., a beagle) that has an impaired gastric capacity (note, the stomach is relaxed with the intake of liquids), determining the gastric capacity (or stomach volume) using a barostat and comparing the change in stomach volume in response to the test compound, see column 9, lines 21-60. The compounds are useful for treating dyspepsia, see column 8, lines 1-16.

Claims 6, 8 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by King (US 5,552,398).

King discloses compounds that are 5-HT-4 antagonists compounds and compositions that are useful in methods of treating dyspepsia, see abstract and column 5. Since claim 4 of the present application states that the compound of claim 1 can be a 5-HT-4 antagonist, and such compounds, compositions and methods are disclosed by King, the claims are anticipated thereby.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje (US 5,912,235) in view of Ui (US 5,000,953).

Hoeltje discloses a method of identifying a compound for treatment of gastric capacity disorders comprising administering a test compound (e.g., an erythromycin A compound) to a dog (i.e., a beagle), as set forth above.

Hoeltje fails to disclose the use of a Wistar rat as the animal in the test.

However, the use of Wistar rats in such animal model methods are well known in the art as being equivalent to the use of a beagle dog for testing the efficacy of test drugs, as shown by Ui, see column 28, lines 23+.

It would have been obvious to one of ordinary skill in the art to substitute the beagles used in the test model method of Hoeltje with Wistar rats because it is known in the art that such rats may be used in an equivalent manner to dogs to provide animal model for testing the efficacy of a test drug, as shown by Ui. One of ordinary skill in the art would have been motivated to employ the equivalent rats to take smaller size.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoeltje (US 5,912,235) in view of King (US 5,552,398)

Hoeltje discloses a method of identifying a compound for treatment of gastric capacity disorders comprising administering a test compound to a dog (i.e., a beagle), as set forth above.

Hoeltje fails to disclose the use of such a test model for other compounds (as claimed in claim 4) that are useful in treating dyspepsia.

King discloses compounds that are 5-HT-4 antagonists are potential compounds for treating dyspepsia, see column 3, lines 41+.

It would have been obvious to employ the methods disclosed by Hoeltje for testing the 5Ht4 antagonists compounds disclosed by King because the Hoeltje methods determine if the test compounds can increase gastric capacity in conditions such as dyspepsia and King teaches new 5HT-4 antagonists which have potential for treating such conditions. One of ordinary skill in the art would have been motivated to test the compounds disclosed by King in methods disclosed by Hoeltje to see which compounds disclosed therein are most effective.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael G. Hartley
Primary Examiner
Art Unit 1616

5/20/2004